

File No: BIO/CT/19/000027
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits Dr. K Anand Kumar of M/s Indian Immunological Limited, Rakshapuram Gachibowli Post Hyderabad Rangareddi Hyderabad (India) - 500032 Telephone No.: 04023000211 FAX: 04023000512 E-Mail: msrs@indimmune.com to conduct clinical trial of the new drug or investigational new drug as per protocol number Protocol No.: HBI/HepA/II/III/2018/002.01.02 Version: 01; Dated : 16 July 2018 Amendment: 02 ; Dated 25 July 2019 in the below mentioned clinical trial sites.

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2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Place: New Delhi
Date: 16-SEP-2019

Annexure:

Details of new drug or investigational new drug:	
Names of the new drug or investigational new drug:	Inactivated Hepatitis A vaccine (Adsorbed) I.P.
Therapeutic class:	Vaccine
Dosage form:	Liquid-Suspension
Composition:	1.0 ml contains Purified and Inactivated Hepatitis A antigen ...NLT 25 IU Aluminium content as (Al(OH) ₃).....NMT 1.25 mg Tween 20....q.s Phosphate buffered saline..... q.s.
Indications:	For active immunization against infections caused by Hepatitis A virus (HAV)

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Department of Community Medicine, School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER), Sector 12, Chandigarh 160 012, India	Institutional Ethics committee, Post Graduate Institute of Medical Education & Research (PGIMER), Sector 12, Chandigarh 160 012, India. ECR/25/Inst/CH/2013/RR-16	Dr. Madhu Gupta,
2	Department of Pediatric Medicine, Institute of Child Health, 11, Dr.Bires Guha street, Kolkata -700017, West Bengal, India	Institutional Ethics committee, Institute of Child Health, 11, Dr.Bires Guha street, Kolkata - 700017, West Bengal, India ECR/359/Inst/WB/2013/RR-16	Dr. Kheya Ghosh Uttam,
3	Department of Pediatrics, Bharati Vidyapeeth (Deemed to be University) Medical College & Hospital , Pune-Satara Road, Katraj-Dhankawadi, Pune-411043, Maharashtra, India	Institutional Ethics committee Bharati Vidyapeeth Deemed University, Bharati Hospital & research Centre, Katraj-Dhankawadi, Pune-411043, Maharashtra, India ECR/313/Inst/MH/2013/RR-16	Dr. Sonali Palkar
4	Shaishav Hospital, Sant Dnyaneshwar Medical Education Research Center,695/A, Sadashiv Peth, Opp.Vijay Talkies, Laxmi Road, Pune, Maharashtra-411030, India	Institutional Ethics committee Sant Dnyaneshwar Medical Education Research Center,695/A, Sadashiv Peth, Opp.Vijay Talkies, Laxmi Road, Pune, Maharashtra-411030, India ECR/127/Inst/MH/2013/RR-16	Dr. Ashish Ramachandra Dhongade
5	Gandhi Medical College and Hospital, Musheerabad, Secunderabad-500003, Telangana, India	Institutional Ethics committee, Gandhi Medical College and Hospital, Musheerabad, Secunderabad-500003, Telangana, India ECR/180/Inst/AP/2013/RR-16	Dr. K. Siva Ram Prasad

6	King George Hospital, Visakhapatnam -530002, Andhra Pradesh, India	Institutional Ethics committee, King George Hospital, Visakhapatnam -530002, Andhra Pradesh, India ECR/197/Inst/KGH/2013/RR -16	Dr. Vasudev Rajapantula
7	JSS Hospital, M.G. Road, Mysuru, Karnataka-570004, India	Institutional Ethics committee, JSS Hospital, M.G. Road, Mysuru, Karnataka-570004, India ECR/387/Inst/KA/2013/RR-16	Dr. Mandyam Dhati Ravi
8	Cheluvamba Hospital, Mysore Medical College and Research Institute, Mysore-570001, Karnataka, India	Institutional Ethics committee, Mysore Medical College and Research Institute, Mysore-570001, Karnataka, India ECR/134/Inst/KA/2013/RR-16	Dr. Pradeep. N.

In addition to point 3, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "A Phase II/III Multicentric Randomized Single Blind Study to Compare the Immunogenicity and Safety of HBI Inactivated Hepatitis- A Vaccine with Havrix® Vaccine when Administered to Two Age Groups of Healthy Subjects" vide protocol number: HBI/HepA/II/III/2018/002.01.02 Version: 01; Dated : 16 July 2018 Amendment: 02 ; Dated 25 July 2019
- II. To submit Ethics Committee approvals of all the participating sites for clinical trial protocol before initiation of the clinical trial.
- III. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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